

# OSSEOINTEGRATION

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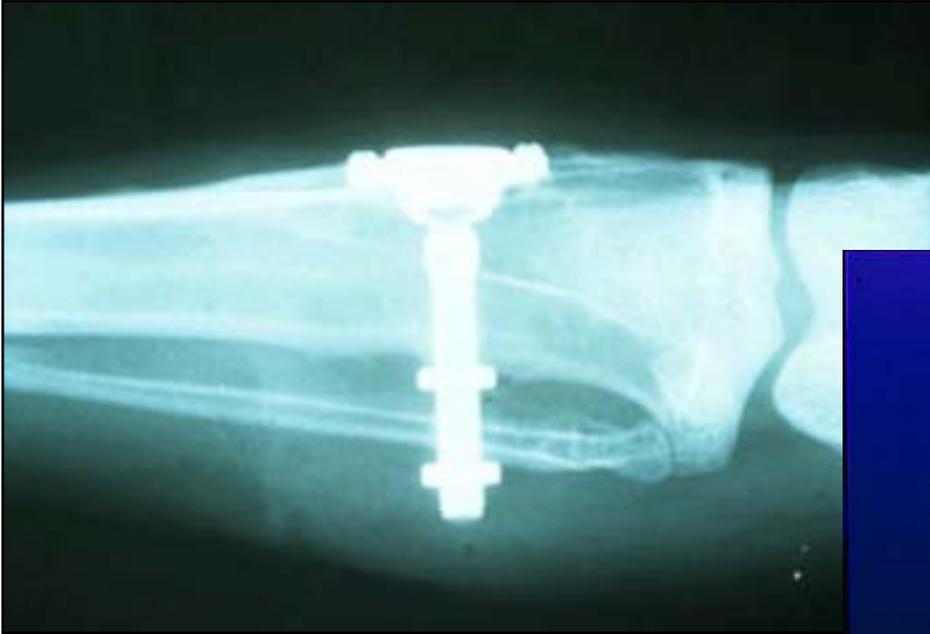
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# History



In 1952 Per-Ingvar Brånemark used a titanium implant chamber to study blood flow in rabbit bone and noted that the chambers could not be removed at the end of the experiment. He called the discovery “osseointegration.”

Os-seo-in-te-gra-tion  
(os"e-o-in"tə-gra'shən)

direct anchorage of an implant by the formation of bony tissue around the implant without the growth of fibrous tissue at the bone-implant interface

*Dorland's Illustrated Medical Dictionary, 28th Ed.*  
(W.B. Saunders Company, 1994)

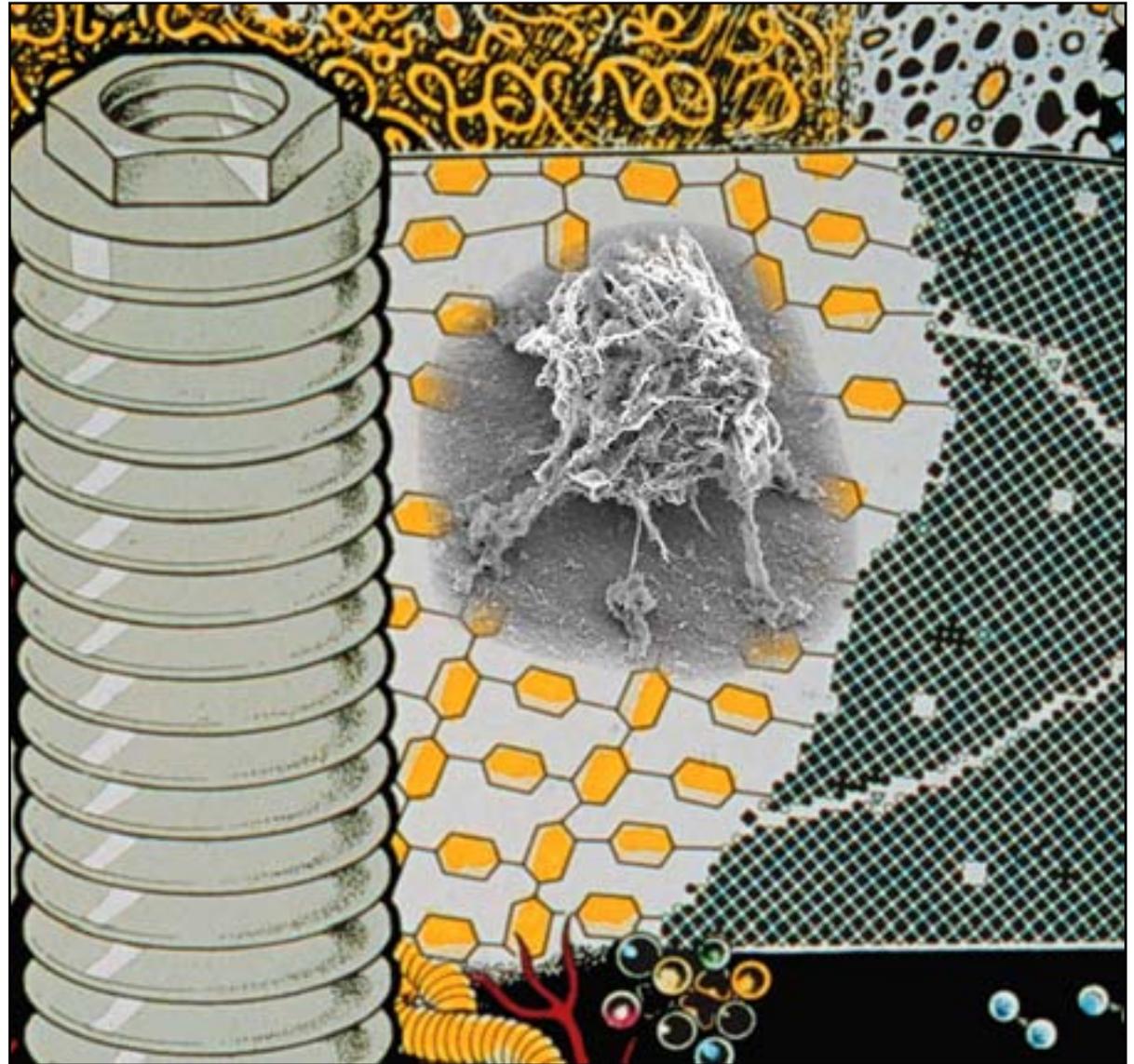


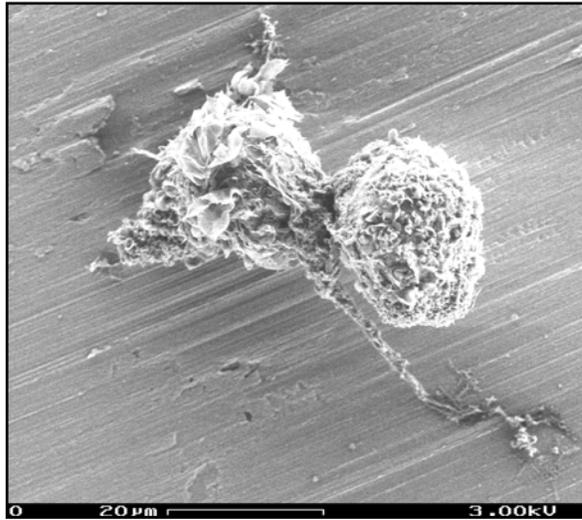
The success of osseointegration is due to the careful surgical technique where, for instance, only low-speed drilling is done, the use of specially designed pure titanium implants, and a careful and controlled period of rehabilitation. This slide shows bone growing within the implant.



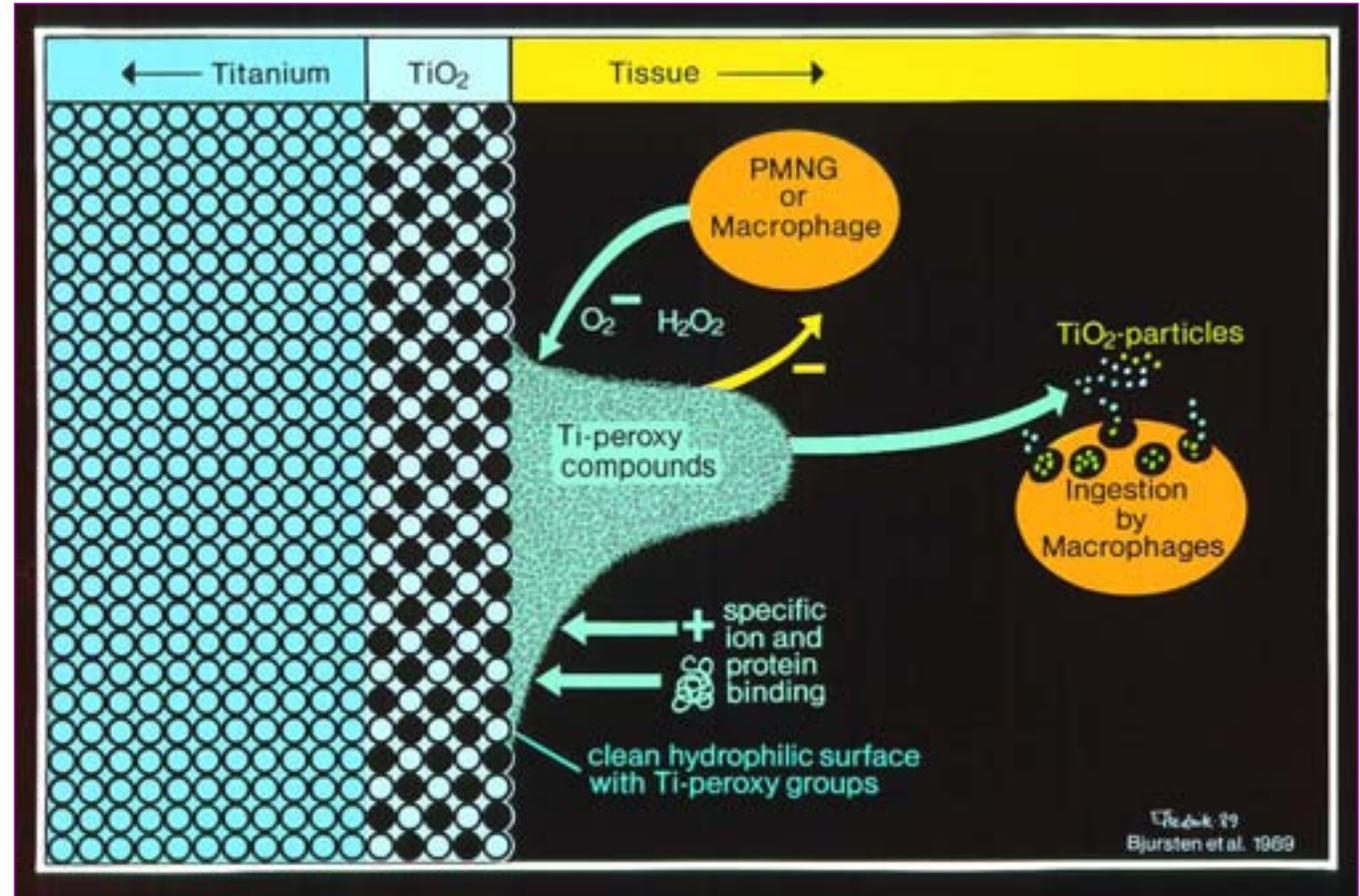
This photomicrograph shows the threads of the titanium implant (left) in direct and intimate contact with bone, which has remodeled to occupy the thread space. Once the bone has formed there is additional time required for it to mature and harden, and this process is also part of osseointegration.

Over 40 Ph.D. dissertations have been conducted in Gothenburg, Sweden to investigate the basic scientific foundations of osseointegration in the dental and orthopaedic sciences. While the scientific basis of osseointegration is not completely understood, it is clear that there is a special relationship between pure titanium that promotes activation of osteoclasts/osteoblasts and bone remodeling.





In fact, the presence of pure titanium may stimulate stem cells to differentiate into osteoblasts, the bone building cells, as this scanning electron micrograph depicts. The cell is in contact with a pure titanium implant.



The surface  $\text{TiO}_2$  layer is extremely inert to corrosion. The Ti-peroxy compound that forms on this layer deactivates inflammatory cells, thus reducing the “foreign body reaction” and enhancing the biocompatibility of pure titanium and the establishment of osseointegration.



A patient with a 30+ year history of osseointegration. Osseointegration was first implemented in the dental sciences in 1965. There are now approximately 1,000,000 people throughout the world with osseointegrated devices.

30 years

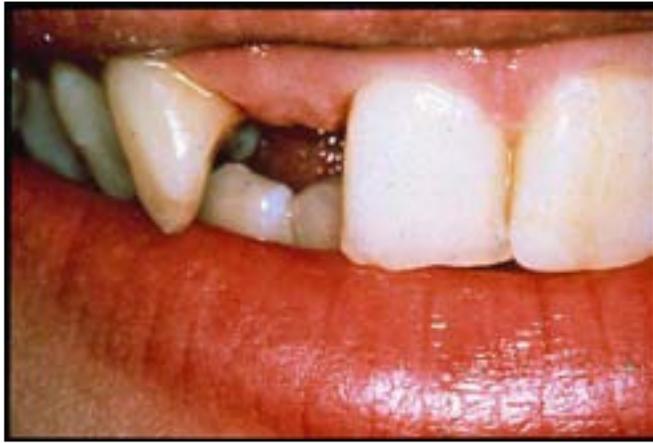
1969

1999

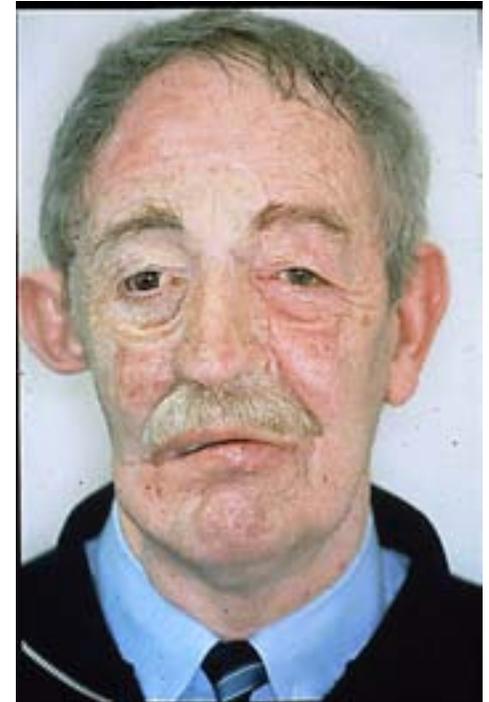
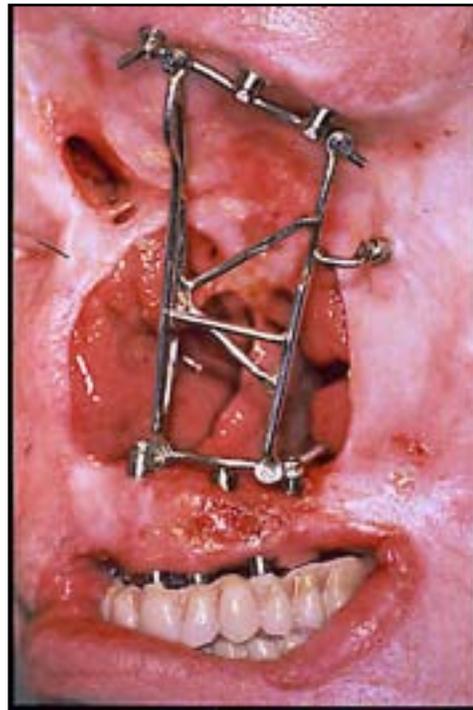
4 fixtures: 3,5 x 5 mm in each jaw

(B.H.) (761216) (990121)

The diagram illustrates the patient's dental history. At the top, a yellow-bordered image shows a dental arch with four fixtures. A horizontal timeline below it marks the years 1969 and 1999. A blue-bordered box contains the text '4 fixtures: 3,5 x 5 mm in each jaw'. Below the timeline are two X-ray images: a red-bordered one on the left and a yellow-bordered one on the right, both showing the fixtures in the jawbone. The labels '(B.H.)', '(761216)', and '(990121)' are positioned at the bottom of the X-ray images.



Osseointegrated dental fixtures can be used to support a single tooth prosthesis, or it can support more complicated prostheses in the cranial facial area, as is shown below. Extensive biomechanical tests have been performed on the stresses affecting these devices.



# What is it like to be a transfemoral amputee?

## Consequences of non-vascular transfemoral amputation-

a survey of quality of life,  
prosthetic use and problems.

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Dep of Orthopaedics, Göteborg University

Sahlgren University Hospital,

Gothenburg, Sweden

This issue is being quantified with scientific techniques;  
See, *Prosthet Orthot Int.* 2001 Dec;25(3):186-94.

# Conclusions

Persons with an established non-vascular unilateral transfemoral amputation...

make extensive use of the prosthesis

have impaired quality of life

have considerable problems related to the amputation and the prosthesis

one fourth consider themselves to have a poor or extremely poor overall situation

Thus,

Improving the physical as well as the psychological well-being for this group of individuals is an important and challenging task!

We think this challenge may be met in *carefully selected individuals* by osseointegrated bone-anchored prostheses.

# Amputation prostheses

## Socket prosthesis

pressure

pain

sores

difficult don/doff

volume changes

new sockets

## Bone anchored prosthesis

no pain

no pressure

easy don/doff

improved function

no remaking

osseoperception

# Early bone-anchored amputation prostheses



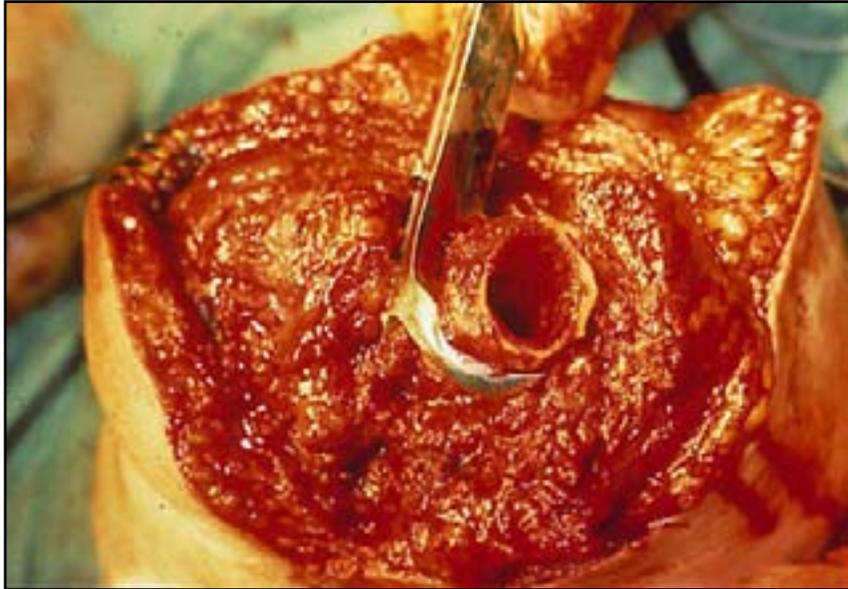
Before osseointegration, the permanent attachment of prostheses to bone was not possible. Early attempts failed because of the formation of fibrous tissue between the implant and bone.

# OSSEOINTEGRATED AMPUTATION PROSTHESES



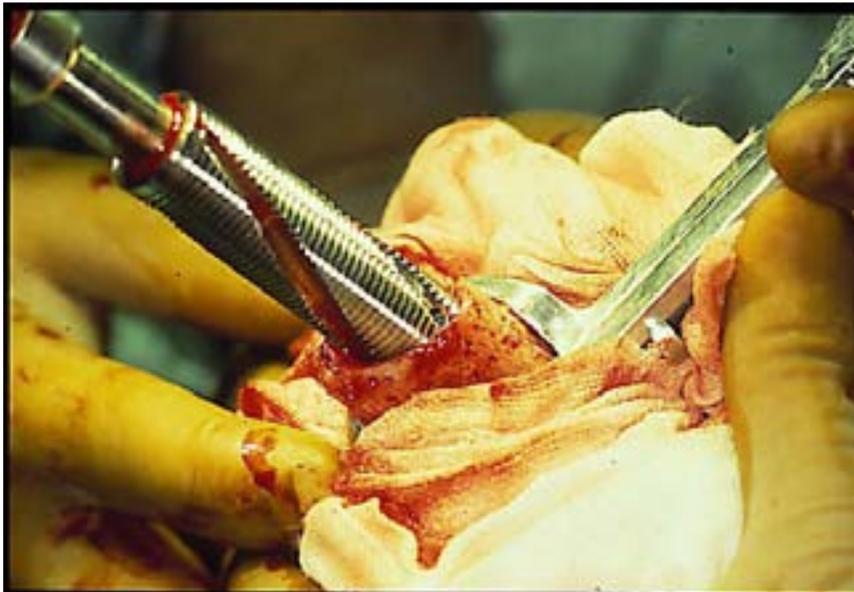
In 1990, the first patient was implanted with a transfemoral osseointegrated prosthesis (bilaterally) in Gothenburg, Sweden. She is now happily married with two daughters and is doing well.

# The surgery is performed in two stages

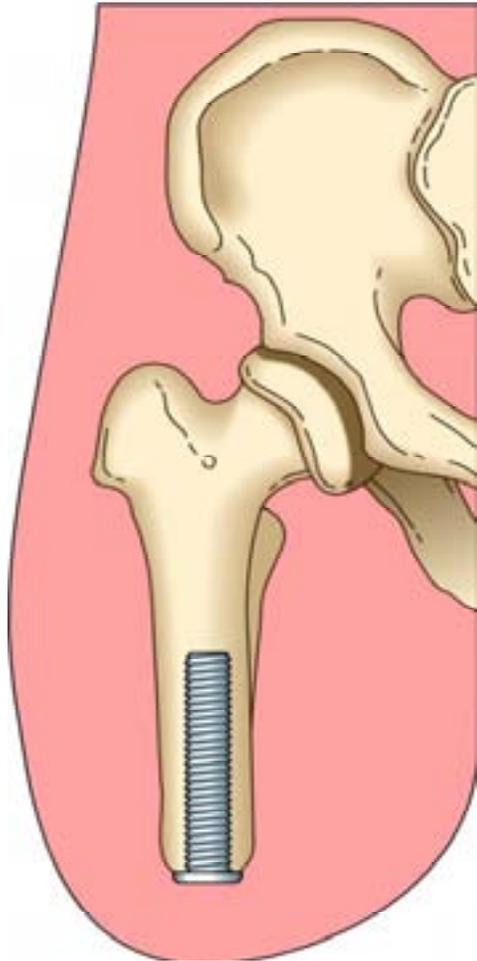


## Stage 1

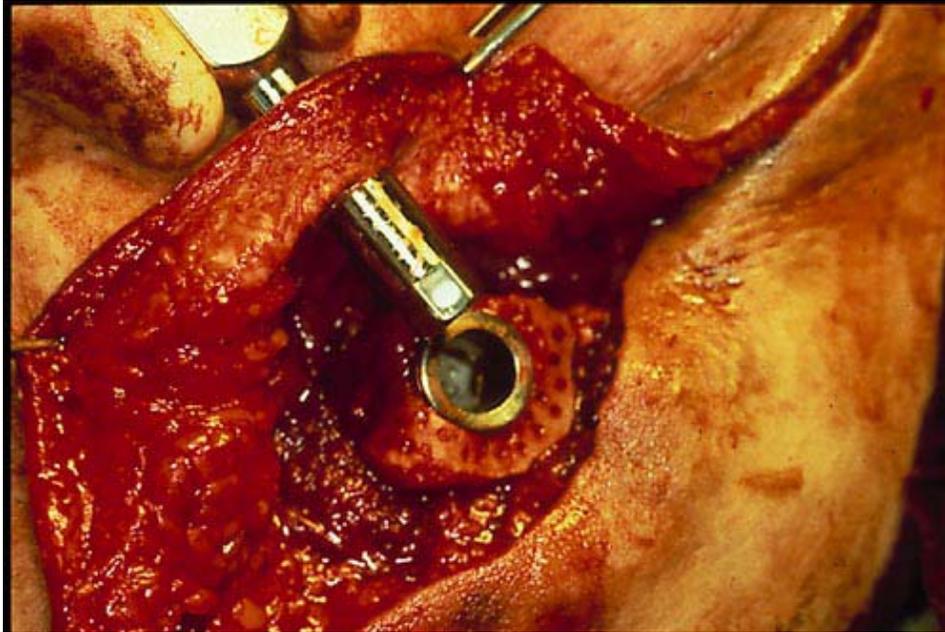
During this initial stage, the femur is prepared as is the muscle tissue and skin. Using a special surgical technique that respects the viability of bone, a specially designed "fixture" is threaded into the medullary cavity. The wound is completely closed.



# Healing phase of osseointegration

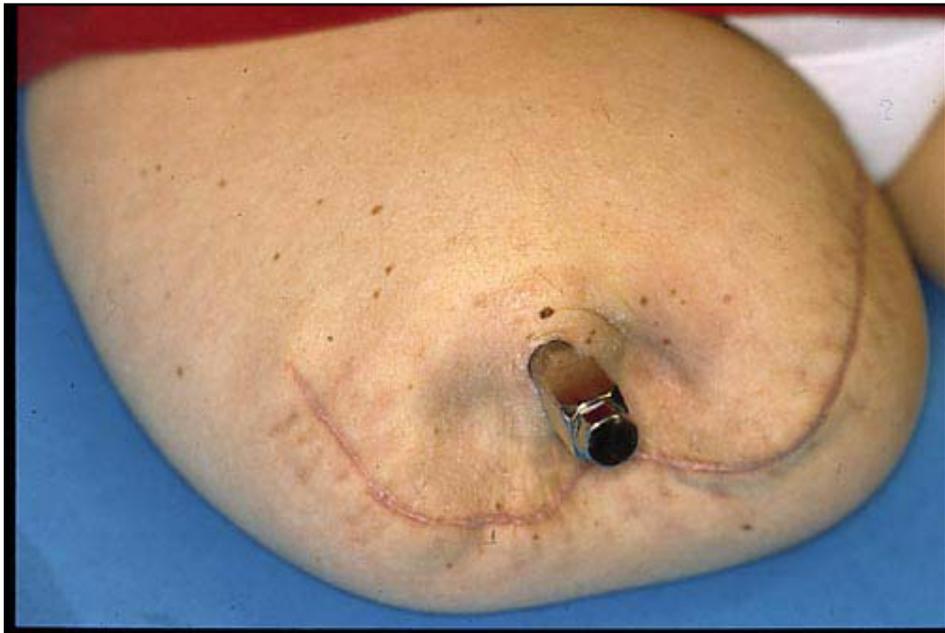


After Stage 1 surgery, it is important that the implant not be loaded until the bone has grown into the threads. Movement of the implant before this time may cause loosening. This phase of osseointegration is normally 6 months, although there is recent unpublished data suggesting that this period may be shortened in selected patients with adequate bone quality. This is in corroboration with dental applications, where it is even possible to start loading immediately.



## Stage 2

During Stage 2 surgery, the implanted "fixture" is reexposed and an "abutment" is connected to the fixture. The abutment is designed to be one of the "fail-safe" components of the system and will break (instead of the fixture) if there were to be excessive loading. The wound is closed with the abutment penetrating the skin. Wound care is routine, and superficial infections sometimes require antibiotics.





## **Mobilization**

This final phase of the osseointegration process typically takes 6 months. During this phase the prosthesis is gradually loaded until the implant can accept full body weight. Thus, the total osseointegration process takes typically 12 months, although in some patients with poor bone quality a longer total rehabilitation time of up to 18 months is required.

# Improved Function

Substantially improved function can be obtained with osseointegrated implants. This patient leads a very active life without concern for skin irritation or socket pain. The prosthesis is interfaced to the abutment with a fail-safe device to further protect the fixture and the bone.

# Professors Brånemark and Myers



There is a long history of scientific collaboration between Professor P.-I. Brånemark and Dr. Rickard Brånemark at Gothenburg University (and the Brånemark Institute) and Professor Robert Myers at the San Diego VA Healthcare Center and the University of California, San Diego.

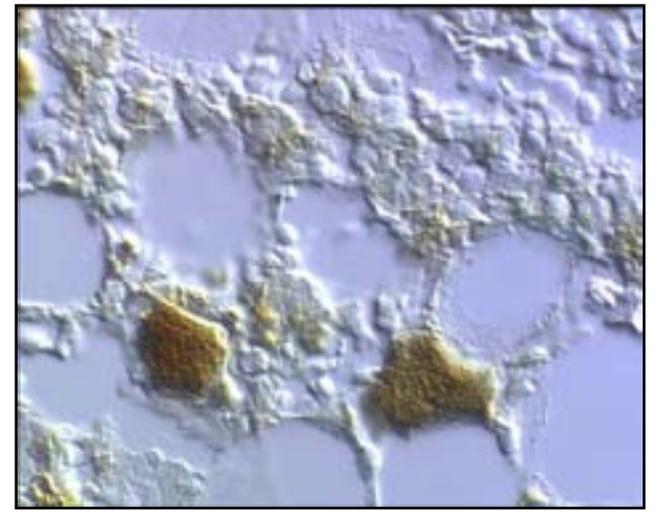
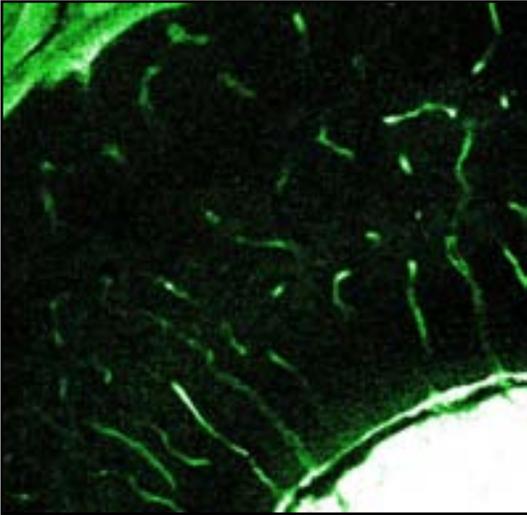
# Osseoperception rat model



In addition to extensive experimental studies in rats, rabbits, and dogs to explore the biomechanics of osseointegrated fixtures, the Gothenburg-San Diego collaboration has established a rat model of transfemoral osseointegration to study the phenomenon of osseoperception.

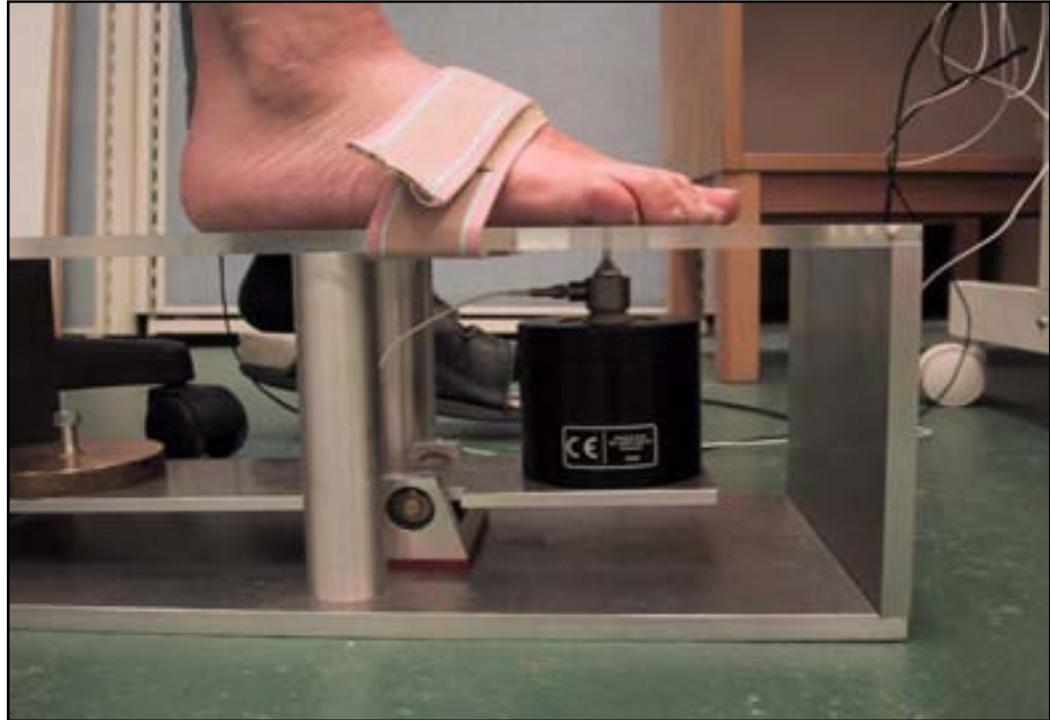
*Ysander, Branemark, Olmarker, Myers, 2001, J Rehabil Res Dev*

# Osseoperception

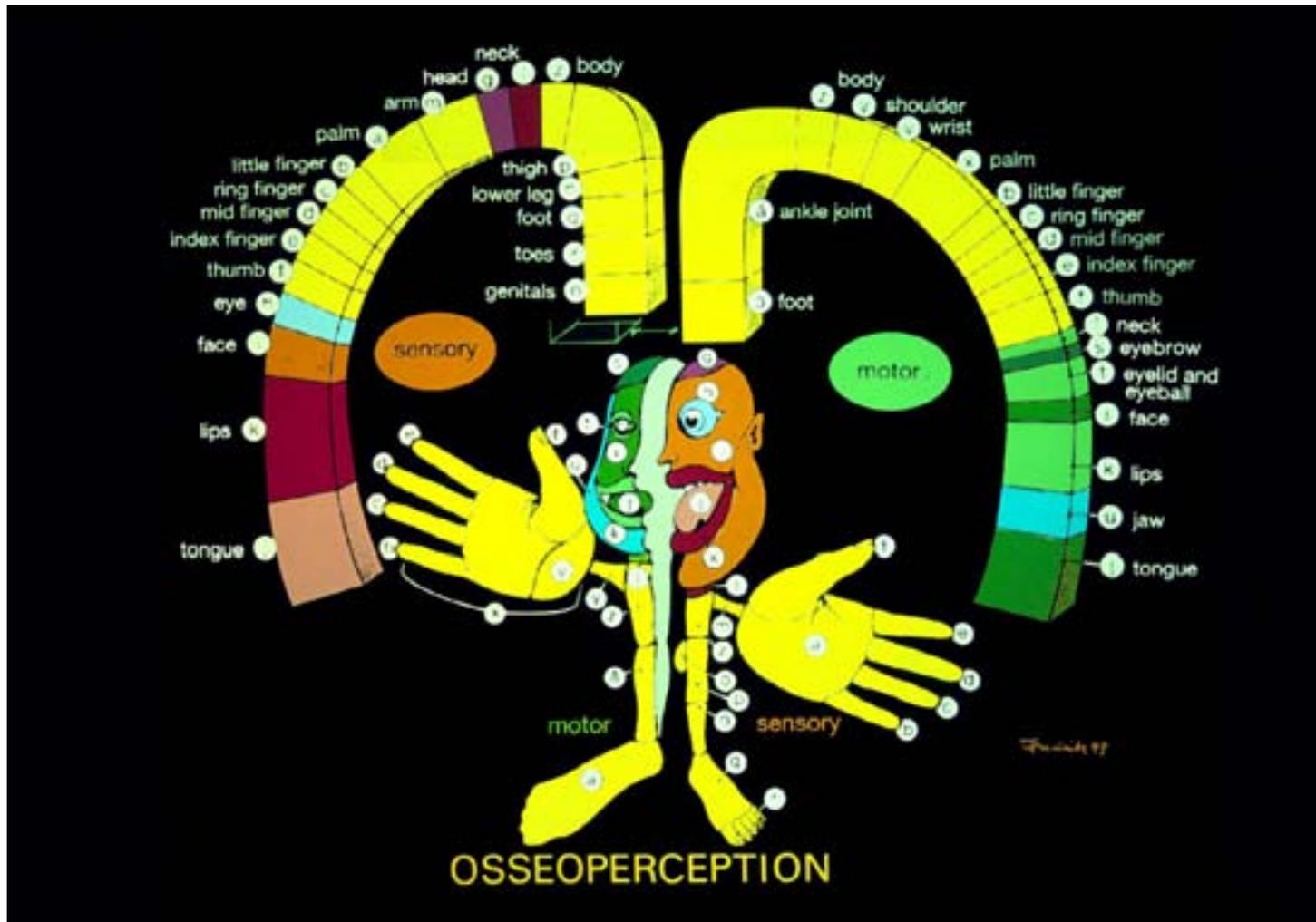


Osseoperception is the term given to the patient-reported feeling of heightened perception of the environment that occurs with osseointegrated prostheses. Research suggests this is secondary to nerve ingrowth into remodeling bone, as controlled by neuropeptides such as calcitonin gene-related peptide (shown here with immunohistochemistry).

# Quantifying Osseoperception



Osseoperception has been quantified using vibrometry as a measure of neural sensory function (*Jacobs et al., Prosthet. Orthot. Int. 2000*).



There is ongoing research work on osseoperception in Sweden and San Diego focused on the relationship between nerve injury and remapping of the somatosensory cortex.

# Development of the OPRA Protocol

## LEARNING GROUP 90-96

Varying

Anatomy

Surgical technique

Healing time

Mobilisation

Custom design

Deep infections/loosening 45 %

Success rate 85 %

A human-use protocol for the **Osseointegration of Prostheses for Rehabilitation Amputees (OPRA)** has been developed and approved in Sweden, Norway and the EU. It is a work-in-progress since 1990. Approximately 75 patients have been implanted as the protocol has developed. Outcome success has continually improved.

# Development of the OPRA Protocol - 2

## **REFINEMENT GROUP 96-99**

Indications

Surgical equipment

Healing time

Mobilisation

Deep infections/loosening decreasing

Success rate increasing

The second phase of the protocol development refined the patient selection criteria, surgical technique and rehabilitation procedures. This significantly reduced complications.

# Development of the OPRA Protocol - 3

## **ROUTINE GROUP 99-**

Defined indications  
Standardised surgical technique  
Standardised components  
Standardised mobilisation program  
Standardised follow up program  
Safety devices  
Additional surgeons and centres:  
    London, Melbourne, Montreal,  
    San Diego/Long Beach VAs

The current protocol implements a stable procedure with excellent outcomes (although limited in follow-up period) in multiple centers throughout the world. The treatment is approved in the EU. IRB approval in San Diego is pending in preparation for FDA application.

# PATIENTS TO BE CONSIDERED

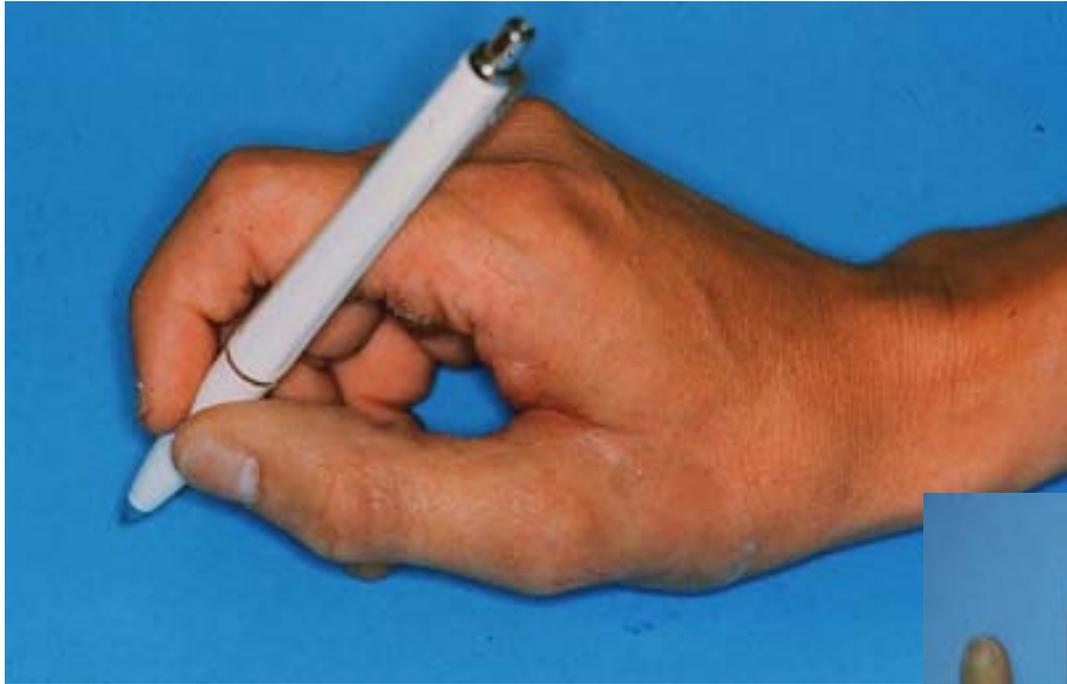
## Amputations in Sweden between 1980-1991

### Diagnoses:

- arteriosclerosis without diabetes 46,4 %
- arteriosclerosis with diabetes 35,3 %
- **trauma** 6,3 %
- **tumour** 2,9 %
- other 9,2 %

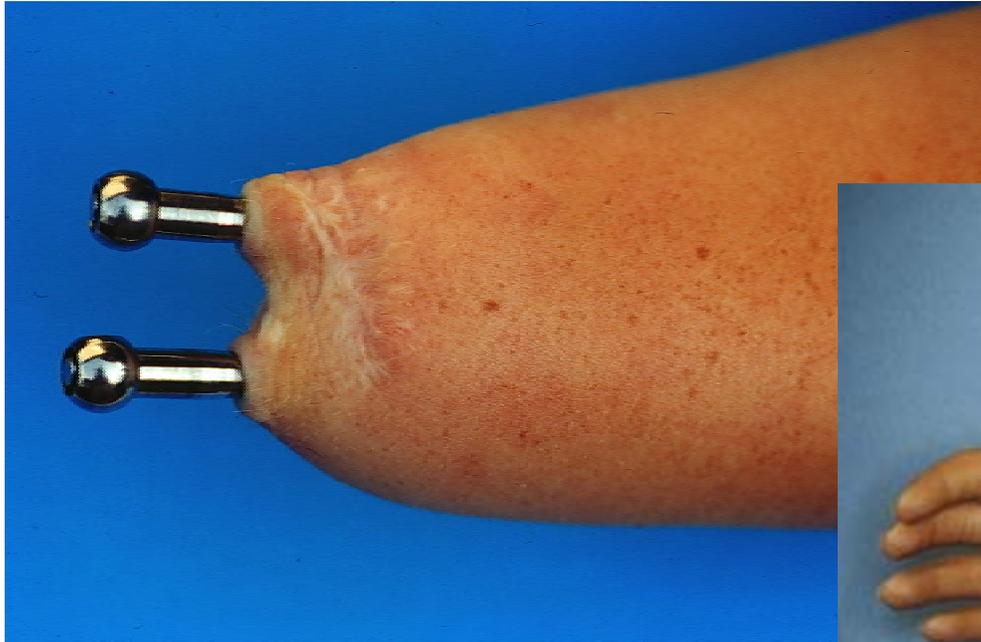


Other uses of osseointegration that might be useful in VA patients include digit attachment (particularly thumb).





The upper limb is also a target for osseointegrated prostheses. Altogether 16 patients in Gothenburg with transradial or transhumeral amputations have received such prostheses since the early 1990s with 15 out of 16 successful.

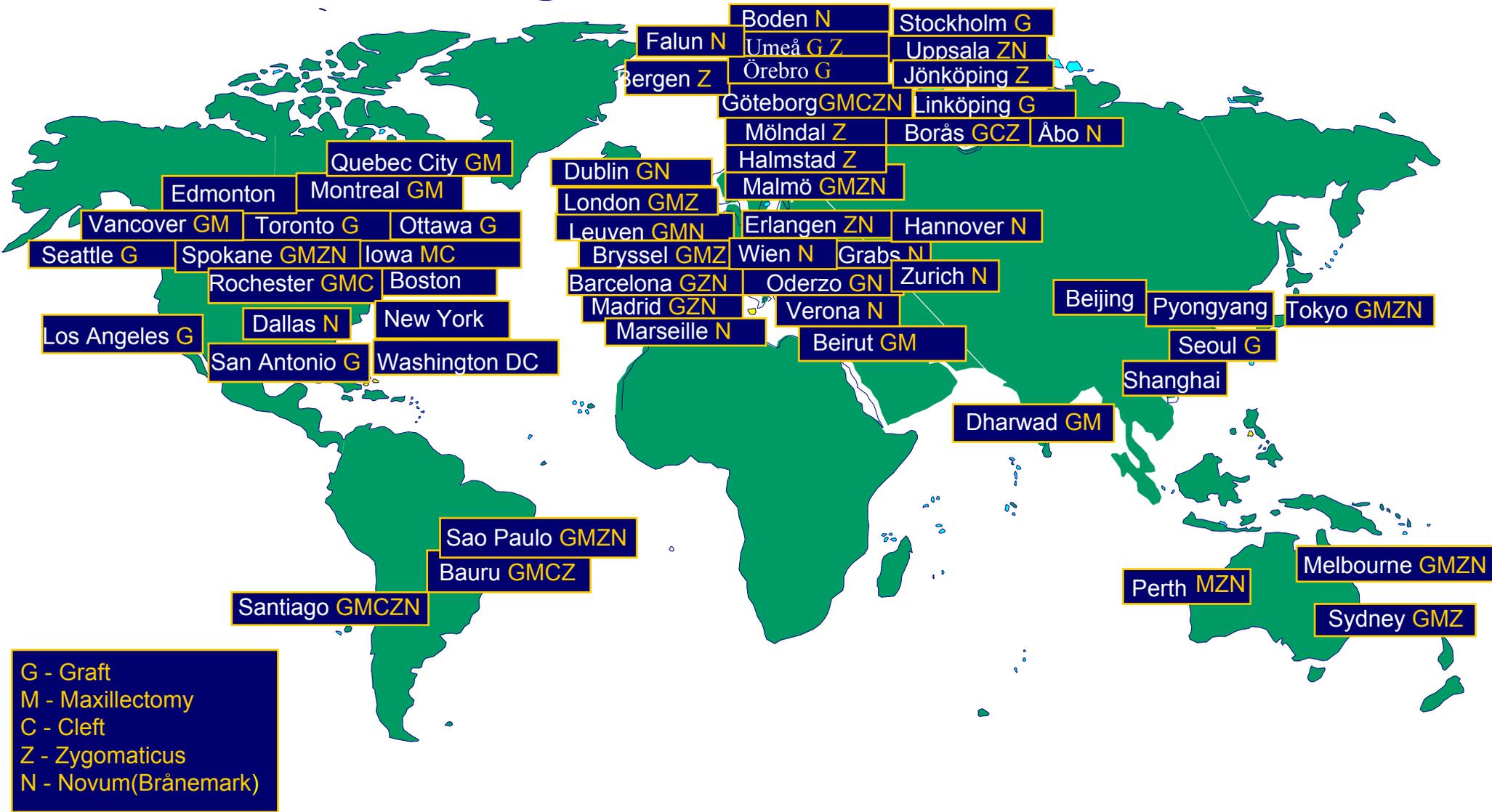


The stable fixation of prosthesis to arm provided by osseointegration enhances the reproducible use of myoelectric interfaces



Transhumeral amputee with osseointegrated prosthesis.

# Osseointegration International



# CONCLUSIONS



Osseointegration is an established medical procedure that is of significant benefit in selected patients with limited traditional options. It is supported by a history of:

- Basic science
- Anchorage and perception
- Dentistry
- CMF
- Orthopaedics



**“I will never use  
a socket prosthesis again.”**

While not fully validated for more wide-spread use in transfemoral amputations from an evidence-based perspective, ongoing clinical trials in the EU and elsewhere outside the USA are providing valuable long-term data for scientific analysis. We believe that in the carefully selected patient it is of value now and can significantly increase the

**QUALITY OF LIFE**

# Thank you!

We recognize that there is a lack of general understanding of the many details concerning the orthopaedic application of osseointegration, caused in part by the relative lack of formal publication of the rapidly changing patient population. One recent publication from the Roehampton group of surgeons trained in transfemoral osseointegration procedures reports on a very limited subset (11) of the total population of patients, which is now 71.

For instance, there has been concern expressed by some about the **divorce rate** in the English population receiving transfemoral osseointegration procedures, but in the larger Swedish population there have been no divorces. Rather, there have been three marriages and four new-born children.

Concerning the issue of **deep infection**, it is recognized that this is a slight yet highly significant potential problem, like death during anesthesia is a very slight but highly significant problem. Using the current OPRA protocol, infection has not been a problem. Only one of 23 patients has had a deep infection, and this patient can again use his osseointegrated prosthesis. The deep infections observed in the early 1990s were presumably secondary to early implant loosening. This hypothesis is supported by the dramatic reduction of deep infections seen following the decrease of early implant loosening.

Concerning the issue of **limb reduction** in failed cases, there has been one very early instance of that in 71 patients. Thus, this potentially significant problem also seems to be of low risk.

Thus, we offer that continued scientific and clinical investigation of orthopaedic osseointegration is at the forefront of the next millennium of rehabilitation care. The traditional socket prosthesis has been used for the past 500 years, and while improving the lives of many patients, it is acknowledged at this conference that research in its further development is imperative.